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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,253	01/26/2005	Samual Weiss	16601-021US1	8661
26181	7590	10/31/2006		
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022				
			EXAMINER MCGILLEM, LAURA L	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/523,253

Applicant(s)

WEISS, SAMUAL

Examiner

Laura McGillem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1/26/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, drawn to a method of producing oligodendrocytes from mammalian multipotent neural stem cells.

Group II, claim(s) 19-20, drawn to a composition of oligodendrocytes and a pharmaceutically acceptable carrier.

Group III, claim(s) 21-30, drawn to a method of providing oligodendrocytes to a mammal.

Group IV, claim(s) 31-40, drawn to a method of treating or ameliorating a demyelinating disease in a mammal.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Applicant's claimed method of producing oligodendrocytes from mammalian multipotent neural stem cells was known in the prior art (See Tennekoon et al. U.S. Patent No. 6,673,606, filed 4/12/2001). Tennekoon et al teach that mesenchymal stromal cells, which are stem-like precursors of non-hematopoietic cells, can differentiate into oligodendrocytes and neurons under appropriate culture conditions by adding or removing various trophic factors to the culture (see column 3, lines 20-25, for example). Tennekoon et al teach that cytokines such as colony stimulating factors can be used as trophic factors to proliferate and differentiate mesenchymal stromal cells into oligodendrocytes (column 6, lines 52-66, in particular).

The technical feature of the method of Group I is the addition of an oligodendrocyte promoting factor to a culture of mammalian multipotent neural stem cells. The technical feature of the method of Group III which distinguishes it from the method of Group I is the step of introducing multipotent neural stem cells into a mammal. The technical feature of the method of Group IV which distinguishes it from the methods of Groups I and III is the step of treating a demyelinating disease by

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administering an oligodendrocyte promoting factor to a mammal. The method of Group IV is distinguished from the methods of Groups I and III, because the method of Group I does not include the step of administering a oligodendrocyte promoting factor to a mammal with a demyelinating disease, and the method of Group III includes the step of transplanting neural stem cells into a mammal with a demyelinating disease which is not a feature of the method of Group IV.

The technical feature of the product of Group II is a composition of oligodendrocytes and a pharmaceutically acceptable carrier. The method of Group IV does not require a pharmaceutical composition of oligodendrocytes. One of the aspects of the method of Group III has the technical feature of introducing neural stem cells into a mammal and therefore does not require the pharmaceutical composition of oligodendrocytes since the method can be performed without the composition. The composition of oligodendrocytes of Group II is distinguished from the method of producing oligodendrocytes of Group I because the composition could be produced using a primary culture of oligodendrocytes from dissected tissue.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD  
10/16/2006

  
DANIEL M. SULLIVAN  
PATENT EXAMINER